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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/523,147 | 10/18/2005 | Thomas Daniel Aicher | X-15515 | 6445 |

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| 25885 | 7590 | 05/25/2007 |
| ELI LILLY & COMPANY | | |
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| EXAMINER | |
| COLEMAN, BRENDA LIBBY | |

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| ART UNIT | PAPER NUMBER |
| 1624 | |

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| NOTIFICATION DATE | DELIVERY MODE |
| 05/25/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/523,147 | Applicant(s) AICHER ET AL. | |
| | Examiner Brenda L. Coleman | Art Unit 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,8,12,13,21,22,27,28,30-33,51,61-64,73-76,85 and 86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,8,12,13,21,22,27,28,30-33,51,61-64,73-76,85 and 86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>1/24/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 7, 8, 12, 13, 21, 22, 27, 28, 30-33, 51, 61-64, 73-76, 85 and 86 are pending in the application.

Election/Restrictions

1. In view of the applicants' amendments and arguments the restriction with respect to the ring systems 5H-dibenzo[b,e][1,5]diazepine, 10H-theino[2,3-b][1,5]benzodiazepine, 4H-thiazolo[5,4-b][1,5]benzodiazepine and 6H-[1]benzothieno[2,3-b][1,]benzodiazepine is herein withdrawn and the claims as amended will be examined in their entirety.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 7, 8, 12, 13, 21, 22, 27, 28 and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 7 recites the limitation "R² substituted phenyl" in the definition of A. There is insufficient antecedent basis for this limitation in the claim.
- b) Claim 8 recites the limitation "(C₁₋₆) alkyl" in the definition of R¹. There is insufficient antecedent basis for this limitation in the claim.
- c) Claim 8 is vague and indefinite in that it is not known what is meant by the definition of R² within the claim where there is no variable R².

- d) Claim 12 recites the limitation "R² substituted thiophenyl" in the definition of A. There is insufficient antecedent basis for this limitation in the claim.
- e) Claim 13 recites the limitation "wherein (C₁₋₄) alkyl is unsubstituted or substituted with a phenyl group" in the definition of R³. There is insufficient antecedent basis for this limitation in the claim.
- f) Claim 13 is vague and indefinite in that it is not known what is meant by the definition of R² within the claim where there is no variable R².
- g) Claim 21 recites the limitation "R² substituted thiazolyl" in the definition of A. There is insufficient antecedent basis for this limitation in the claim.
- h) Claim 22 is vague and indefinite in that it is not known what is meant by the definition of R² within the claim where there is no variable R².
- i) Claim 27 recites the limitation "R² substituted benzothiophenyl" in the definition of A. There is insufficient antecedent basis for this limitation in the claim.
- j) Claim 28 is vague and indefinite in that it is not known what is meant by the definition of R² within the claim where there is no variable R².
- k) Claim 86 is vague and indefinite in that it is not known what is meant by the moiety 2-methoxymethyl in the nomenclature of the species where there is no 2-position on a methyl group.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1624

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 7, 8, 12, 13, 21, 22, 30-33, 51, 61-64, 73-76, 85 and 86 are rejected

under 35 U.S.C. 103(a) as being unpatentable over Tehim et al., U.S. Patent No.

5,824,676. The generic structure of Tehim encompasses the instantly claimed

compounds (see Formula I, column 1) and for the same uses as claimed herein.

Example 4 differs only in the nature of the R₁, R₃ and/or R₄ substituents. Column 1, line

62 through column 2, lines 1-5 defines the substituents as follows: R₁ is C₁₋₆alkyl

optionally substituted with a substituent selected from OH, halo, C₁₋₄alkyl and C₁₋

₄alkoxy; R₂ and R₃ are independently selected from H or C₁₋₆alkyl optionally substituted

with a substituent selected from OH, halo, C₁₋₄alkyl and C₁₋₄alkoxy. Compounds,

compositions and method of use of the compounds of formula I of the instant invention

are generically embraced by Tehim in view of the interchangeability of R₁, R₂ and R₃

substituents of the piperazine ring system. Thus, one of ordinary skill in the art at the

time the invention was made would have been motivated to select for example

ethoxymethyl, hydroxyethyl, etc. as well as other possibilities from the generically

disclosed alternatives of the reference and in so doing obtain the instant compounds in

view of the equivalency teachings outlined above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Brenda L. Coleman
Primary Examiner Art Unit 1624
Thursday, May 17, 2007